FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA

Inspiring Trust, Assuring Safe & Nutritious Food

GMP - Good Manufacturing Practices

&

SSOP: Sanitation Standards Operating Procedures

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Training Program for FSOs

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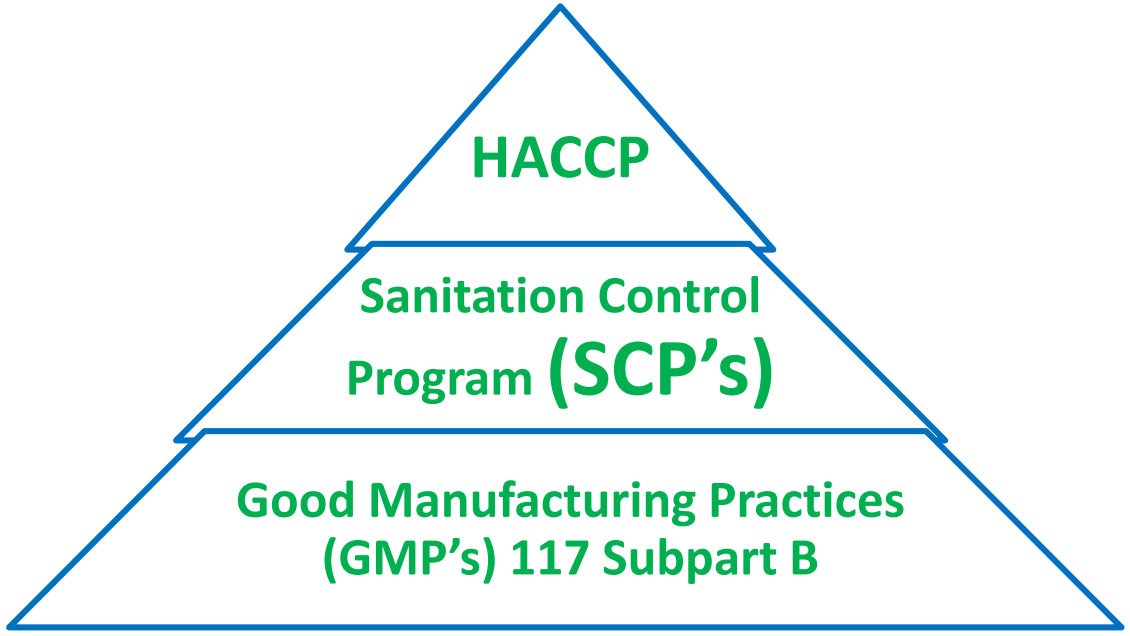
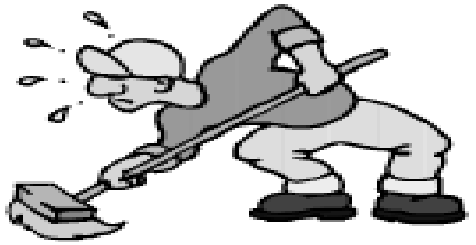
Importance of Prerequisite programme

- HACCP is not a stand alone system
- Hazard control requires from plant and personnel.
- Environment control
- Transportation control
- Recall programme
- Supplier control
- Preventive maintenance

Pre-requisite Programs (cGMP / SSOP)

Programs that provide basic operational condition for safe food production – often in place before HACCP implementation.





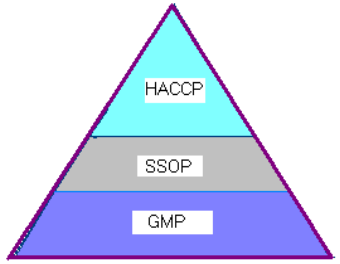
HACCP is not a stand-alone system. It is built on a foundation of Good Manufacturing Practices and Sanitation Control Procedures.

Pre-requisite Programs (PRP)

❖Programs that must be in place BEFORE starting HACCP
❖Foundation for implementation of HACCP system as it is not stand alone system

- ✓ Employee training & training records: 21CFR 117 sub part A & F
- ✓ Current Good manufacturing Practices (GMPs): 21CFR 117 subpart B
- ✓ Sanitation control Procedures: 21 CFR 123.11

➢Procedures, including GMP and SSOP that address operational conditions in the processing plant and provide the foundation for the HACCP system .



21 CFR 123

21 CFR 123.11

21 CFR 117

➢GMPs provide the foundation for the safe food supply.
➢SSOPs are steps or procedures that control certain in-plant conditions

Besides GMP and SSOP, Traceability, Recall and Allergen management program must be in place for successful implementation of HACCP system

21 CFR part 117 - cGMP

- **117.10: Personnel**
- **117.20: Plant & Grounds**
- **117.35: Sanitary Operation**
- **117.37: Sanitary Facilities & Controls**
- **117.40: Equipment & Utensils**
- **117.80: Processes and Controls**
- **117.93: Warehousing & Distribution**
- **117.95: Holding & Distribution of by-products for use as animal food**
- **117.110: Defect Action levels**

117.10: Personnel

a. Disease Control

b. Cleanliness

Disease control

- Person (either by medical examination or by supervisory observation) having illness/open wound, boils, sores or any abnormal source of microbial contamination shall be excluded from handling of food/food-contact surfaces/food packaging materials.
- Personnel shall be instructed (trained) to report above stated illness to their supervisors.
- Health history of food handlers i.e. Health cards

Cleanliness

All Persons handling of food/food-contact surfaces/food packaging materials shall conform to hygienic practices while on duty.

Some examples of hygienic practices…..

1. **Suitable outer garment which protect against contamination**
2. **Adequate personal cleanliness**
3. **Washing & sanitizing hands**
4. **Removing unsecured jewelry**
5. **Using cleaned, intact, sanitized, impermeable gloves.**

Cleanliness cont…..

6. Wearing effective hair restraints (net/beard cover etc.)

7. Storing clothing & other belongings in areas other than where food is exposed or where utensils are washed.

8. Confining the activities like eating food, chewing gum, drinking beverages or using tobacco etc to the areas other than the area where food is exposed or where utensils are washed.

9. Precautions to protect against contamination of food/food-contact surfaces/packaging materials from perspiration, hair, cosmetics, tobacco, chemicals, medicines etc.

Education & Training

- Personnel should be competent (background of education or experience or both) for identifying sanitation failure.

- Food handlers/supervisors should receive appropriate training (mainly on handling techniques/protection principles/consequence of poor hygienic practices).

Supervision

- Responsibility for assuring compliance shall be clearly assigned.

Building & Facilities

I. Plant & Grounds

II. Sanitary operations

III. Sanitary facilities & controls

117.20. Plant & Grounds

A. Plant construction & Design:

should be constructed in such a manner that:

√ Provide sufficient space (each area, between equipment & walls)

√ Prevent potential contamination (location/partition/air flow etc..)

√ Easy to clean/maintain/repair (Floor/walls/ceilings)

√ Prevent contamination from drip/condensate(fixtures/ducts/pipes)

√ Provide adequate lighting including hand washing & toilet etc)

√ provide adequate ventilation

√ provide adequate protection against entry of pests.

(e.g. U trap/mesh - drainage; mesh – exhaust fan

Air curtain/ strip curtains – Door/chute)

B. Grounds:

Adequate maintenance that will prevent harborage of pests -

- ✓ **properly removing litter, waste, cutting grass or any structure that may attract pest.**
- ✓ **maintaining roads, yards.**
- ✓ **proper drainage (no water stagnation).**
- ✓ **waste treatment/disposal in adequate manner.**

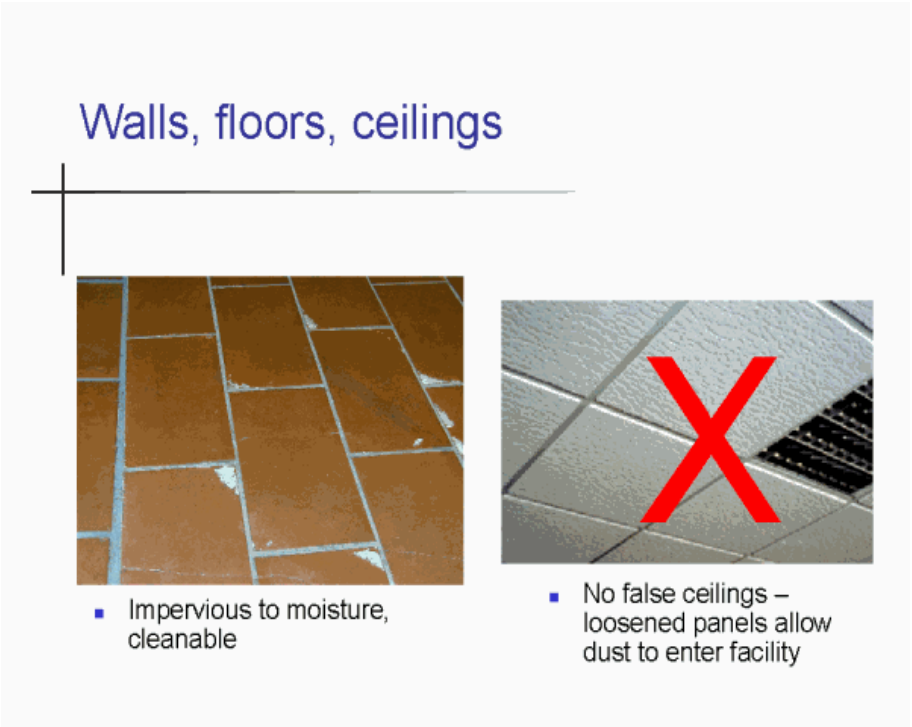
117.35: Sanitary Operations

a. General Maintenance
b. Substances used in cleaning & sanitizing; storage of toxic material
c. Pest control
d. Sanitation of food contact surfaces
e. Storage and handling of cleaned portable equipment & utensils

117.35: Sanitary Operations .cont…

a. General Maintenance

- ✓ **All physical facilities of plant shall be maintained in a sanitary condition.**
- ✓ **Cleaning and sanitizing of equipment & utensils shall be conducted in a manner that protects against contamination of food/ food contact surfaces/ packaging materials.**


Walls, floors, ceilings
Impervious to moisture, cleanable
No false ceilings – loosened panels allow dust to enter facility

117.35: Sanitary Operations cont….

b. Substances used in cleaning & sanitizing

- ✓ shall be safe & free from undesirable microorganisms
- ✓ shall have traceability (supplier's guarantee/CoA etc.)
- ✓ Toxic chemicals shall be identified, held and stored.

C. Pest Control

- ✓ No pests shall be allowed
- ✓ effective measures shall be taken to exclude pests
- ✓ use of insecticides/rodenticides is permitted only under precautions & restrictions

117.35: Sanitary Operations cont....

D. Sanitation of food-contact surfaces:

- ✓ food contact surfaces shall be cleaned & sanitized before & after use and any interruption during which surface may get contaminated.
- ✓ Sanitizing agents shall be adequate and safe for use.
- ✓ Non-food-contact surfaces need to clean as frequently as necessary to protect against contamination of food.

E. Storage and handling of cleaned portable equipment & utensils:

- ✓ Cleaned and sanitized equipment (with food contact surfaces) & utensils should be stored in a proper location & manner that protects from contamination.

117.37: Sanitary Facilities & Controls

a. Water Supply

b. Plumbing

c. Sewage disposal

d. Toilet facilities

e. Hand washing facilities

f. Rubbish & Offal Disposal

117.37: Sanitary Facilities & Controls cont…

a. Water Supply:

√ Shall be safe & adequate sanitary quality

√ Shall be sufficient for operation

√ Running water - suitable temp & pressure (for cleaning)

b. Plumbing:

√ shall be adequately designed and installed to carry sufficient quantities of water.

√ shall not provide back flow

√ shall not have cross connection with non-potable/waste water pipe line.

117.37: Sanitary Facilities & Controls cont…

C. Sewage disposal

√ Plant shall have adequate & proper sewage disposal system

√ Adequate sewerage system

D. Toilet Facilities:

√ shall provide adequate no. of toilets

√ shall be readily accessible

√ shall maintain in sanitary condition & good repair

√ shall have self-closing door

√ shall not open directly to food handling areas

117.37: Sanitary Facilities & Controls cont…

E. Hand washing facilities:

√ shall be adequate and convenient and furnished with running water facility

√provided at suitable locations

√ provided with effective sanitizers

√ suitable drying facility

√ suitable device/fixture to avoid splash

√ Readily understandable signboards directing employees to wash before start of work

√ provide suitable receptacles to keep single-used articles

F. Rubbish & Offal disposal

√ Shall be conveyed, stored and disposed properly to minimize development of odor and shall not be attractant/harborage of pests.

117.40: Equipment & Utensils

Design, construction & installation in such a way-

- ✓ Shall be adequately cleanable
- ✓ Preclude adulteration (lubricants/metal fragments etc)
- ✓ Corrosion resistant
- ✓ Made of non toxic material (must be food grade)
- ✓ Withstand intended use (e.g. cooker belt for temp > 90°C)
- ✓ Seams of utensils shall be smoothly bonded to minimize accumulation of food particles, dirt etc
- ✓ Temp. controlled equipment (e.g. Cold store, cooker) shall be fitted with temp. indicator, recording device and automatic temp. regulator or alarm
- ✓ Instruments used for measuring/recording shall be accurate (calibrated)

117.80: Processes & Control

- √ All operation (receiving to shipment) shall be conducted in accordance with adequate sanitation principle.
- √ Appropriate quality control operation shall be employed to ensure food is suitable for human consumption.
- √ Overall hygiene and sanitation shall be under supervision of one or more competent individuals.
- √ testing procedures (chemicals/biological etc.) shall be used to identify sanitation failure.
- √ Contaminated/adulterated food shall be rejected or reprocessed (if permissible) to eliminate the contamination.

117.93: Warehousing & distribution

- Storage & transportation of finished food shall be under condition that protect food against physical/ chemical/ microbiological contamination.
- Protect from deterioration of food & damage to packaging
- Air curtains to doors and chutes of cold storages and ante-rooms
- Temperature recording devices, alarm bells
- Direct loading to pre-cooled shipping containers
- Periodical cleaning of cold storages etc.

117.95 Holding and distribution of human food by-products for use as animal food.

Ensure that human food by-products intended for use as animal food are handled safely when no further manufacturing or processing is performed by the human food processor.

Human food by-products must be **held under conditions that prevent contamination**. Containers and equipment used must be suitably designed, made of appropriate materials, properly cleaned, and well maintained. The by-products must be protected from contamination sources such as trash and must be **clearly and accurately identified** during holding.

When distributed, the by-products must be **labeled with their common or usual name**, either affixed to or accompanying the product.

Shipping containers and bulk transport vehicles (such as totes, drums, tubs, or bulk carriers) must be **examined prior to use** to ensure they do not contaminate the by-products, when the facility transports the product itself or arranges transportation through a third party.

Overall, it emphasizes **proper holding, identification, labeling, and transportation controls** to maintain the safety of human food by-products used as animal food.

117.110 Defect action levels.

(a) The manufacturer, processor, packer, and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(b) The mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food

RM & ingredients

√ shall be inspected to ascertain suitable for process

√ shall be washed with water of adequate sanitary quality

√ containers used for handling shall be inspected to ensure it does not contribute contamination

√ shall not contain levels of micro organisms that may produce food poisoning

√ shall not contain natural toxins

√ shall be free from pests

√ shall be held at suitable temp. to avoid adulteration.

√ Rework shall be done in a manner which prevent adulteration (e.g. no running water during thawing of frozen material)

Manufacturing operations

- √ Shall be conducted to minimize microbial growth/ contamination/ decomposition and shall be passed to subsequent steps without delay to minimize microbial growth. (control: T/T)
- √ effective measures to protect finished food from contamination by raw material/ingredients/offal etc. (control: Partition/chute).
- √ equipment & utensils used for hold/work in progress that prevent contamination (control: partition/color coding).
- √ effective measures shall be taken to protect against inclusion of metal/glass/other extraneous matter.
- √ Contaminated product shall be disposed or reworked in such a manner that protect against contamination of other food.
- √ Reconditioning (re-processing) method shall be effective and food shall be re-examined to conform before incorporating into other food.
- √ mechanical manufacturing steps (washing/peeling/cutting etc) shall be performed in a manner that prevent contamination(control: running water, T/T)

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SSOP-sanitation standard operating procedure (21 CFR 123.11)

Establishment shall have Written SSOP plan

- Specific procedure each location
- Person responsible
- Monitoring condition & practices with laid down frequency
- Corrections in timely manner & corrective action plan
- Verification plan
- Maintain records
- Training program for employees

Key points in records

1. Name & Address of processor 2. Date & time of monitoring

3. Space for observation & CA 4. Signature with date

Eight Key points of SSOP

1. Safety of water & Ice
2. Condition & Cleanliness of food contact surfaces
3. Prevention of cross contamination
4. Maintenance of hand washing /toilet facilities
5. Protection of food & food packaging materials from adulterants.
6. Proper labeling, storage of toxic compounds.
7. Control of employees health conditions
8. Exclusion of pests

Safety of water/ice

Key points:

- **Source of water/ice**
- **Treatment**
- **Storage & transport**
- **Prevention of chance of contamination (potable- non potable ; back flow)**
- **Cleaning of storage tanks**
- **Quality checks (physical/chemical/bacteriological with frequency)**

Condition & Cleanliness of food contact surfaces

Key points:

- **It must include table, utensils, freezing tray, packing materials (poly sheets/bags), IQF belt, hand, gloves, outer garments etc.**
- **contact surfaces shall be smooth, non-toxic (i.e. no leasing of chemicals), non-absorbent, corrosion free, inert to cleaning/sanitizing chemicals.**
- **Monitoring –**
  - **physical – condition & cleanliness**
  - **Chemical – type/concentration**
- **Verification – swab testing**

Cleaning steps

- Pre clean
- Pre rinse
- Cleaning
- Rinsing
- Disinfection
- Post rinse
- Storage
- Check efficiency

Effectiveness of cleaning

It depends on:

- **Form (solid/powder/liquid)**
- **Type (alakline/acidic/enzymatic)**
- **Contact time**
- **Temperature**
- **Concentration**
- **Water chemistry**

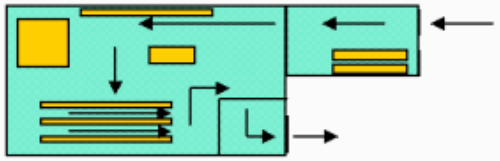
Prevention of cross contamination

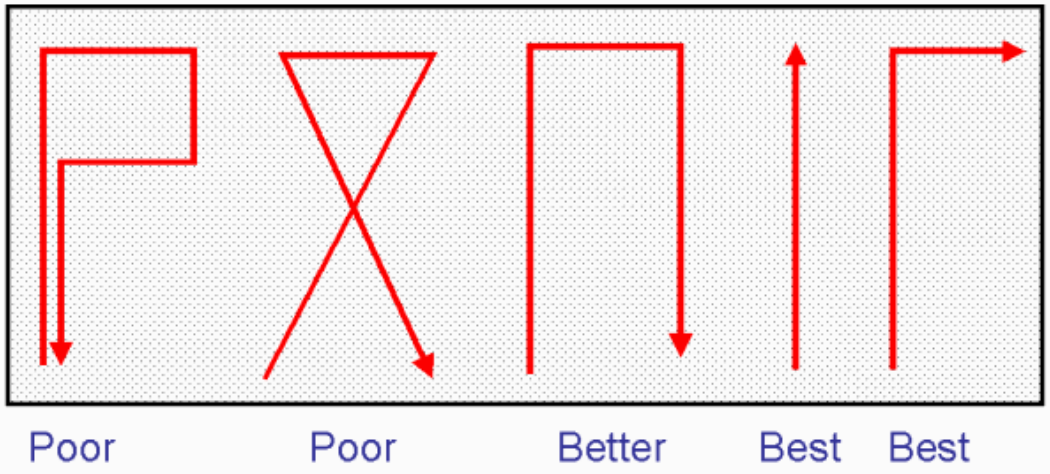
How to achieve:

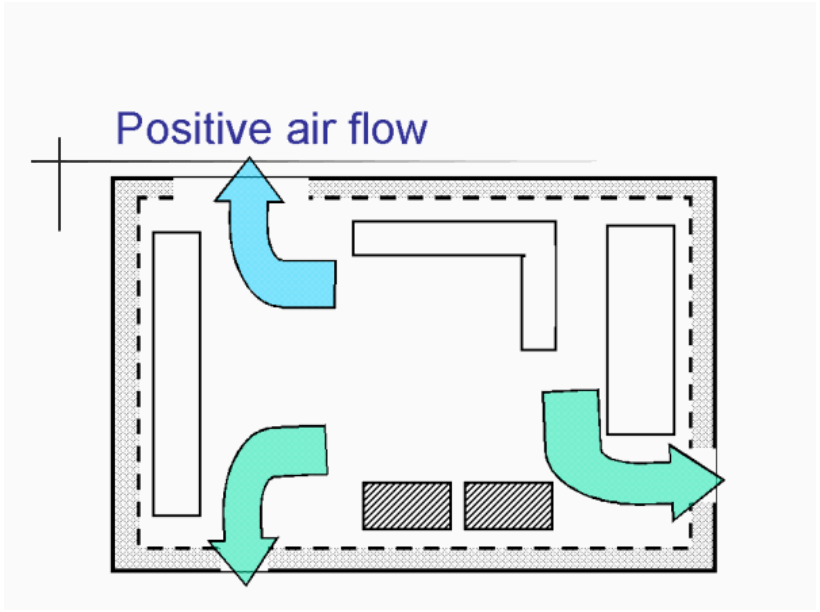
- Plant design (separation, chute)
- Employee flow (through change room)
- Product flow (low risk to high risk)
- Air flow
- Drainage water flow (high risk to low risk)
- Restrict eating/chewing gum/tobacco etc
- Awareness/training

Preferences for product flow directions

(from Troller, Sanitation in Food Processing)





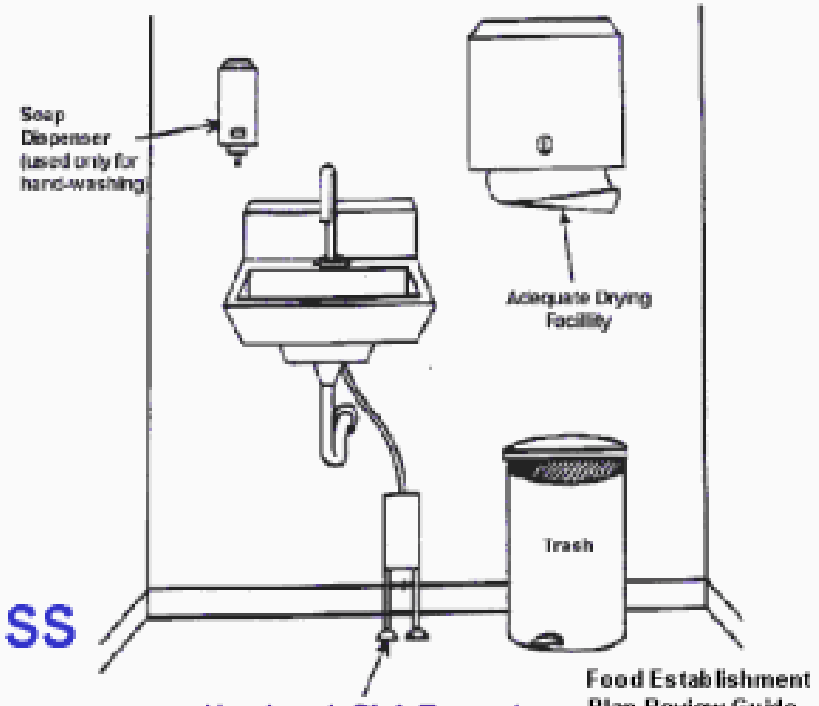


Maintenance of hand washing /toilet facilities

- Facility at strategic points
- Sufficient number w.r.t. no.of employees
- Provision to prevent recontamination after washing (e.g. non-hand operating tap)
- Awareness/ training for proper washing
- Check/verify at laid down frequency

Each operation should provide a sufficient number of accessible and well furnished toilet facilities maintained in a sanitary condition and kept in good repair at all times

- Soap dispenser
- Paper towels
- Hot water
- Sink working properly
- Trash removed
- General cleanliness



Handwash Sink Example

Food Establishment Plan Review Guide - FDA, 2000

How to wash hands

- Remove jewellery & Watch
- Wet hands with warm water (43ºC)
- Lather and rub using warm water
- Rinse with running potable water
- Dry with disposable paper/cloth towels
- Avoid contamination after washing
- Dip hands in 20 ppm chlorine solution with 20-30 sec contact time
- Rinse hand with running water facility

When to wash and sanitize the hands

Beginning a shift.

After handling raw ingredients

After handling non-food items.

After touching hand or face

After using rest room

After eating or drinking

After using the toilets

After coughing ,Sneezing etc.

After using a handkerchief or tissue paper etc.

After handling soiled/unsanitary equipments or utensils

Protection of food & food packaging materials from adulterants

- Design & lay out (seepage/condensation)
- Storage & use of food-grade and non-food grade

Proper labeling, storage of toxic compounds

- Labeling of container – original & working
- Use of toxic chemicals - prohibited in production area
- Shall be kept under control of identified person with locking system

Control of employees health conditions

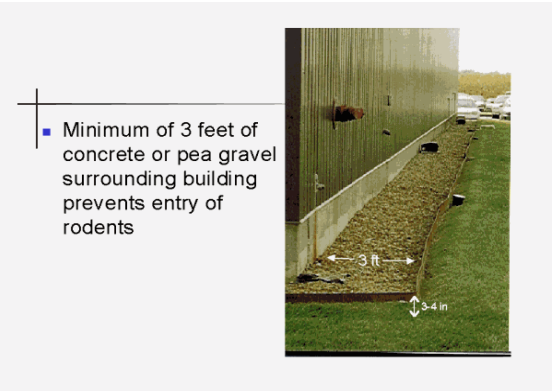
- Initial health check up
- Vaccination
- Stool/urine culture for sal/v.c
- Pre-operative check
- Reporting
- First aid facility

Exclusion of Pests

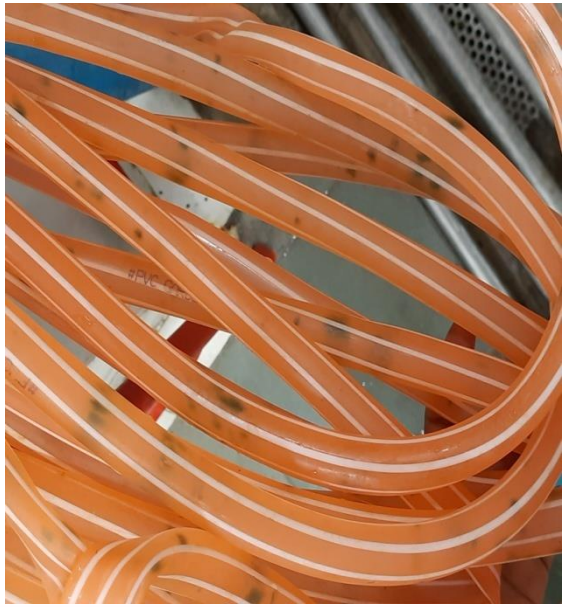
Schedule should cover all areas

Internal program (pest ‘O’ flash, automatic air curtains; self-closing doors, drain mesh, exhaust fan mesh, etc)

External program – contract with outside agency for spray/fumigation/bait etc



Few Observation



Product Recall

Definition: Removing Products which are adulterated /misbranded from market and distribution channels.

- **Classification of recall:**
  1. **Class – I**
  2. **Class – II**
  3. **Class – III**
- **Formation of recall action team:**
  - **Name with 24 hr contact number**
  - **Role/responsibility of each individual shall be defined clearly**
  - **Alternate member shall be designated for each individual**
  - **Representation from various department**
- **Recall Procedure:**

Classification of Recall

Class –I:

Product deficiency may cause serious threat to health or life

needs quick removal from marketing and distribution channels

Example: Food containing botulinum toxin.

Class II:

Product deficiency may cause temporary or medically reversible adverse health consequences

products must be removed from all levels in the distribution chain

Example: Food containing Salmonella

Class III:

Deficiency will not have adverse health consequences (health hazard)

Products must be removed from the wholesale levels.

Examples: Improperly labeled or products with filth contamination.

Recall Procedure

- Product complaint form: Should include customer name, product, code (production date), defects, action to be taken etc.
- Initiation of recall & notify regulatory agency: Should include reason for recall, product information, distribution details
- Internal notification: For team members to follow
- Preparation of public notice:
- Confirmation letter to customer:
- Product recovery & disposition:
- Termination of recall

Allergen Management Program

1. Allergen/sensitive ingredient listing

- Allergenic protein (Egg, Fish, Milk, Peanut, Crustaceans, Bivalves, Soy, Tree nuts, Wheat, Sesame seed etc.)
- Sensitive ingredients (Sulphites, Yellow #5, Monosodium glutamate etc)

2. Conducting an hazard analysis for ingredients /packaging material

3. Develop control plan

Allergen Control Plan

It must include following:

- Receiving & storage control
- Product formulation
- Equipment
- Production scheduling
- Production
- Re-process
- Clean-up
- Labeling control
- Employee training
- Verifying/validating plan

Thank You